EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1216050-1

Manufacturer: WILAmed GmbH
Aurachhöhe 5-7
91126 Kammerstein
Germany

Products: Medical devices for respiration therapy

Replaces Certificate, Registration No.: HD 60128634 0001

Products included:

- Breathing Tubes
- Breathing Sets Heated
- Breathing Sets Unheated
- Respiratory Ventilators for adults and infants
- Respiratory Ventilators for neonates and pediatrics
- Heated Humidifiers
- Humidification Chambers
- Breathing Masks
- Exhalation Valves
- Catheter Mount

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

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TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.